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Garden City, N	IY 11530		ART UNIT	PAPER NUMBER
			1656	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dknoell@ssmp.com sanofi_docketing@ssmp.com betty@ssmp.com

Application No. Applicant(s) 10/076.632 HABERMANN, PAUL Office Action Summary Evaminar Art Unit David J. Steadman 1656 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 09 December 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 22-24,30-32 and 35-41 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 22-24,30-32 and 35-41 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO 948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date

4) Interview Summary (PTO-413)
Paper No(s)/Mall Date

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Status of the Application

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/9/10 has been entered.

- [2] Claims 22-24, 30-32, and 35-41 are pending in the application.
- [3] Applicant's amendment to the claims, filed on 12/9/10, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [4] Applicant's remarks filed on 12/9/10 in response to the final Office action mailed on 8/9/10 have been fully considered and are deemed to be persuasive to overcome at least one of the rejections and/or objections previously applied. Rejections and/or objections previously applied to claim 33 are withdrawn solely in view of the amendment to cancel claim 33.
- [5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objections

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[6] The objection to claim 31 in the recitation of "Bn is 1-15 codons, when n is an integer from 1 to 15, or a chemical bond, when n=0;" is <u>withdrawn</u> in view of the instant claim amendment.

- [7] The objection to claim 23 in the recitation of "(E) repeating (B) and (C) several times" is withdrawn in view of the instant claim amendment.
- [8] Claim 41 is newly objected to under 37 CFR 1.75 as being a substantial duplicate of claim 36. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The differences between the methods of claims 22-24 and 30 and the methods of claims 37-40, respectively are shown below.

Claims	Px	Sx	Host cell
22-24 and 30	yeast ADH2 promoter	α factor leader sequence	unlimited
37-40	Unlimited	Unlimited	yeast

Claim 36 limits the host cell of claims 22-24 and 30 to a yeast host cell and claim 41 limits Px and Sx of claims 37-40 to a yeast ADH2 promoter and a nucleic acid encoding an α factor leader sequence, respectively. As such, the methods of claim 41 are substantial duplicates of the methods of claim 36.

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[9] Claims 22, 24, 30, 37, 39 and 40 are newly objected to in the recitation of "protein(Y) is a nucleic acid sequence encoding mini-proinsulin; R in As_mR is an..." and in the interest of improving claim form and maintain consistency with claims 23 and 38, it is suggested that the noted phrase be amended such that the phrase "R in As_mR is an..." begins on a separate line immediately below "and As_mR is 1-10 codons when m=1-10, respectively;", *i.e.*, to recite:

"As_m is a chemical bond or codon, wherein m=0-10; As_m is a chemical bond when m=0, and As_m is 1-10 codons when m=1-10, respectively;

R in As_mR is an arginine codon or a chemical bond; protein(Y) is a nucleic acid sequence encoding mini-proinsulin; and T is an untranslated expression-enhancing nucleic acid sequence".

Claim Rejections - Double Patenting

[10] Claim 31 and 35 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Patent 7,638,618 B2 (hereafter "618 patent"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). In view of the recitation of the transitional phrase "comprising" in claim

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31, each of the individual moieties of the nucleic acid of claim 31, *i.e.*, Px, Sx, etc., can include additional unrecited elements. The difference between claim 1 of the '618 patent and claims 31 and 35 herein is that claims 31 and 35 require Px to be a yeast ADH2 promoter and Sx to be an alpha factor leader sequence, otherwise, claim 1 of the '618 patent anticipates claims 31 and 35 of this application when Z_1 or Z_2 of claim 1 the '618 patent is a codon for arginine.

Claims 31 and 35 cannot be considered patentably distinct over claim 1 of the '618 patent when there is a specifically disclosed embodiment in the '618 patent that supports claim 1 of the patent and falls within the scope of claims 31 and 35 herein because it would have been obvious to one of ordinary skill in the art to include a yeast ADH2 promoter sequence as Px and an alpha factor leader sequence as Sx in claim 1 of the '618 patent by selecting a specifically disclosed embodiment that supports that claim. See, e.g., column 6, lines 32-35 of Example 1 of the '618 patent, which specifically exemplifies a nucleic acid encoding a hirudin-miniproinsulin fusion protein with a yeast ADH2 promoter sequence and an alpha factor leader sequence. One of ordinary skill in the art would have been motivated to include a yeast ADH2 promoter sequence and an alpha factor leader sequence because that embodiment is specifically disclosed as a working example within claim 1 of the '618 patent.

[11] Claims 22-24, 30, 36-41 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-6 of the '618 patent in view of Dörschug et al. (US Patent 6,875,589; cited in the PTO-892 mailed on

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12/12/08; hereafter "Dörschug"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The difference between claims 5-6 of the '618 patent and claims 37-40 herein is that claims 37-40 are drawn to methods of producing a fusion protein using a nucleic acid, whereas claims 5-6 of the '618 patent are drawn to a yeast host cell comprising the same nucleic acid. However, in view of the teachings of Dörschug, this difference would appear to be an obvious variation. Dörschug teaches fermentation of a veast host cell comprising a veast expression vector encoding a fusion protein comprising mini-proinsulin (e.g., column 10, Example 7); teaches precipitating undesired elements from the supernatant by adjusting the pH to 3.5 (column 10, lines 61-65); teaches "releasing" prior to isolating mini-proinsulin (column 2) and teaches preparation of insulin from mini-pro-insulin using a combination of trypsin and carboxypeptidase B (column 12, lines 11-22). In view of the precedent of Dörschug, it would have been obvious to use the yeast host cell of claims 5-6 of the '618 patent to fermentatively produce a hirudin-mini-proinsulin fusion protein and prepare the resulting hirudin-mini-proinsulin fusion protein according to Dörschug. One would have been

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motivated and would have had a reasonable expectation for doing this because of the teachings of Dörschug.

Alternatively, claims 22-24, 30, and 41 cannot be considered patentably distinct over claims 5-6 of the '618 patent when there is a specifically disclosed embodiment in the '618 patent that supports claims 5-6 of the '618 patent and falls within the scope of claim 41 herein because it would have been obvious to one of ordinary skill in the art to include a yeast ADH2 promoter sequence as Px and an alpha factor leader sequence as Sx in the nucleic acid of the yeast host cells claims 5-6 of the '618 patent by selecting a specifically disclosed embodiment that supports that claim. See, e.g., column 6, lines 32-35 of Example 1 of the '618 patent, which specifically exemplifies a nucleic acid encoding a hirudin-miniproinsulin fusion protein with a yeast ADH2 promoter sequence and an alpha factor leader sequence. One of ordinary skill in the art would have been motivated to include a yeast ADH2 promoter sequence and an alpha factor leader sequence because that embodiment is specifically disclosed as a working example within claims 5-6 of the '618 patent.

RESPONSE TO REMARKS: At p. 13 of the instant remarks, applicant states that a terminal disclaimer will be filed to overcome this rejection after the examiner determines the claimed subject matter to be allowable. This is not found persuasive and the rejection is maintained.

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[12] Claims 37-40 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 11-12, 15, and 17 of US Patent 7,202,059 B2 (hereafter "'059 patent") in view of Dörschug (*supra*) and Schmid et al. (US Patent 5,919,895; cited in the PTO-892 mailed on 12/12/08; hereafter "Schmid"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The differences between claims 2, 11-12, and 17 of the '059 patent and claims 37-40 herein are:

- claims 37-40 of this application require protein(Y) to be mini-proinsulin, whereas "Y" of the '059 patent is pro-insulin or insulin;
- claims 37-40 of this application require a Lys or Arg codon (moiety Z) before
 Hir, which is not required in the claims of the '059 patent;
- 3) claims 37-40 of this application require the host cell to be a yeast host cell; whereas claims 2, 11-12, and 17 of the '059 patent are generic with respect to the host cell;

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4) claims 37-38 of this application require adjusting the pH of the supernatant to about 2.5 to 3.5 to precipitate non-desired proteins, whereas claim 13 of the '059 patent recites a precipitation step, yet does not expressly recite adjusting the pH to about 2.5 to 3.5;

- 5) claim 39 of this application requires a "releasing" step prior to concentrating the protein encoded by Y, whereas the fermentation methods of claims 11-12 of the '059 patent do not require a "releasing" step prior to concentrating the protein encoded by Y; and
- claim 40 of this application requires "releasing" by treating the fusion protein with trypsin and carboxypeptidase B.

However, in view of the teachings of the references of Dörschug and Schmid, these differences would appear to be obvious variations of the claims of the '059 patent. Regarding difference 1), Dörschug teaches mini-proinsulin is a form of pro-insulin with a shortened B or C chain and is easily converted to insulin (column 1, lines 8-34). Regarding difference 2), Schmid teaches the advantage of placing an Arg at the N-terminus of a recombinantly expressed hirudin allows for removal of a fused signal sequence with trypsin (column 2, line 66 to column 3, line 1). Regarding difference 2), Dörschug teaches expression of a mini-proinsulin fusion protein using a yeast host cell and expression vector (e.g., columns 9-10, Examples 6-7). Regarding difference 4), Dörschug teaches precipitating undesired elements from the supernatant by adjusting the pH to 3.5 (column 8, lines 4-6; column 10, lines 61-65). Regarding difference 5), claim 17 of the '059 patent expressly recites a "releasing" step prior to isolating insulin.

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Regarding difference 6), Dörschug teaches preparation of insulin from mini-pro-insulin using a combination of trypsin and carboxypeptidase B (column 12, lines 11-22).

Therefore, in view of the noted teachings of Dōrschug and Schmid, it would have been obvious to modify the nucleic acid and method of the '059 patent to: 1) encode Arg at the N-terminus of Hir; 2) for "Y" to be mini-proinsulin; 2) produce the fusion protein using a yeast host cell and expression vector; 3) produce the fusion protein using a yeast host cell and expression vector; 4) adjust the pH of the supernatant to 3.5; 5) to release mini-proinsulin prior to concentrating by enzymatic or chemical cleavage; and 6) treating mini-proinsulin with trypsin and carboxypeptidase B for conversion to insulin. One would have been motivated to make such modifications in order to: 1) allow cleavage of the hirudin moiety from the signal sequence as taught by Schmid; 2) the prior art recognizes yeast as a suitable expression host for a mini-proinsulin fusion protein; 3) because mini-proinsulin is an art-recognized form of proinsulin as taught by Dŏrschug; 4) to remove undesired elements from the supernatant as taught by Dŏrschug; 5) release the elements of the fusion protein; and 6) convert mini-proinsulin to insulin as taught by Dŏrschug, respectively.

[13] Claims 22-24, 30-32, 35-36, and 41 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 4, 11-12, 15, and 17 of the '059 patent in view of Dörschug (*supra*), Schmid (*supra*), and Badziong et al. (US Patent 5,866,371; hereafter "Badziong"). An obviousness-type double patenting rejection is appropriate where the conflicting claims

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are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other. Regarding claims 31 and 35, the differences between claims 2 and 4 of the '059 patent and claims 31 and 35 herein are:

- claim 31 of this application requires protein(Y) to be mini-proinsulin, whereas
 of the '059 patent is pro-insulin or insulin;
- claim 31 of this application requires a Lys or Arg codon (moiety Z) before Hir, which is not required in claim 2 of the '059 patent; and
- 3) claim 31 of this application requires Px to be a yeast AHD2 promoter and Sx to be a nucleic acid encoding an alpha factor leader sequence, whereas P and S of claim 2 of the '059 patent are generic with respect to the promoter and nucleic acid encoding a signal sequence.

However, in view of the teachings of the references of Dörschug, Schmid, and Badziong, these differences would appear to be obvious variations of the claims of the '059 patent. Regarding difference 1), Dörschug teaches mini-proinsulin is a form of proinsulin with a shortened B or C chain and is easily converted to insulin (column 1, lines 8-34). Regarding difference 2), Schmid teaches the advantage of placing an Arg at the N-terminus of a recombinantly expressed hirudin allows for removal of a fused signal

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sequence with trypsin (column 2, line 66 to column 3, line 1). Regarding difference 3), Dörschug teaches a yeast expression vector encoding a yeast alpha factor precursor sequence (column 9, Example 6; column 3, lines 18-25; Figures 2a and 2b), which is considered to be a nucleic acid encoding an alpha factor leader sequence and Badziong teaches the use of a yeast ADH2 promoter (ADHII in Badziong) for recombinant expression of miniproinsulin and hirudin in yeast, which results in high yields (column, lines 16-20; column 3, lines 10-12).

Therefore, in view of the noted teachings of Dörschug, Schmid, and Badziong, it would have been obvious to modify the nucleic acid of the '059 patent to: 1) have "Y" be mini-proinsulin; 2) encode Arg at the N-terminus of Hir; and 3) for P and S to be a yeast ADH2 promoter and an alpha factor leader sequence, respectively. One would have been motivated to make such modifications and to have a reasonable expectation of success because: 1) the prior art recognizes yeast as a suitable expression host for a mini-proinsulin fusion protein; 2) Arg at the N-terminus of Hir allows cleavage of the hirudin moiety from the signal sequence as taught by Schmid; and 3) the use of yeast ADH2 promoter and an alpha factor leader sequence for high yield production of a heterologous protein is shown by the prior art.

Regarding claims 22-24, 30, 36, and 41, in addition to differences 1) to 3) addressed above, the differences between claims 2, 11-12, and 17 of the '059 patent and claims 22-24, 30, 36, and 41 herein are:

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4) claims 36 and 41 of this application require the host cell to be a yeast host cell; whereas claims 2, 11-12, and 17 of the '059 patent are generic with respect to the host cell;

- 5) claims 22-23 of this application require adjusting the pH of the supernatant to about 2.5 to 3.5 to precipitate non-desired proteins, whereas claim 13 of the '059 patent recites a precipitation step, yet does not expressly recite adjusting the pH to about 2.5 to 3.5;
- 6) claim 24 of this application requires a "releasing" step prior to concentrating the protein encoded by Y, whereas the fermentation methods of claims 11-12 of the "059 patent do not require a "releasing" step prior to concentrating the protein encoded by Y; and
- claim 30 of this application requires "releasing" by treating the fusion protein with trypsin and carboxypeptidase B.

However, in view of the teachings of the references of Dörschug, Schmid, and Badziong, these differences would appear to be obvious variations of the claims of the '059 patent. Regarding difference 4), Dörschug and Badziong teach expression of a mini-proinsulin protein using a yeast host cell and expression vector (e.g., columns 9-10, Examples 6-7). Regarding difference 5), Dörschug teaches precipitating undesired elements from the supernatant by adjusting the pH to 3.5 (column 8, lines 4-6; column 10, lines 61-65). Regarding difference 6), claim 17 of the '059 patent expressly recites a "releasing" step prior to isolating insulin. Regarding difference 7), Dörschug teaches

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preparation of insulin from mini-pro-insulin using a combination of trypsin and carboxypeptidase B (column 12, lines 11-22).

Therefore, in view of the noted teachings of Dörschug, Schmid, and Badziong, it would have been obvious to modify the nucleic acid and method of the '059 patent to: 4) produce the fusion protein using a yeast host cell and expression vector; 5) adjust the pH of the supernatant to 3.5; 6) to release mini-proinsulin prior to concentrating by enzymatic or chemical cleavage; and 7) treating mini-proinsulin with trypsin and carboxypeptidase B for conversion to insulin. One would have been motivated to make such modifications and would have had a reasonable expectation of success because: 4) the prior art recognizes yeast as a suitable host for high level heterologous protein expression; 5) to remove undesired elements from the supernatant as taught by Dörschug; 6) release the elements of the fusion protein as recited in claim 17; and 7) convert mini-proinsulin to insulin as taught by Dörschug.

Regarding claim 32, in addition to differences 1) to 7) addressed above, the difference between claim 2 of the '059 patent and claim 32 herein is: 8) claim 32 requires a sequence encoding Gly-Asn-Ser-Ala-Arg between the sequences encoding hirudin and protein Y moieties. Claim 32 cannot be considered patentably distinct over claim 2 of the '059 patent when there is a specifically disclosed embodiment in the '059 patent that supports claim 2 of the patent and falls within the scope of claim 32 herein because it would have been obvious to one of ordinary skill in the art to include a sequence encoding Gly-Asn-Ser-Ala-Arg between the sequences encoding hirudin and protein Y moieties by selecting a specifically disclosed embodiment that supports that

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claim. See, e.g., column 7, lines 62-64, which discloses a nucleic acid encoding a hirudin-proinsulin fusion protein with a sequence encoding Gly-Asn-Ser-Ala-Arg between the sequences encoding hirudin and proinsulin. One of ordinary skill in the art would have been motivated to include a sequence encoding Gly-Asn-Ser-Ala-Arg between the sequences encoding hirudin and protein Y moieties because that embodiment is disclosed as a working example within claim 2 of the '059 patent.

RESPONSE TO REMARKS: Beginning at p. 12 of the instant remarks, applicant argues claim 33 is not rejected over the claims of the '059 patent and the rejection is obviated by incorporating the limitations of claim 33 into claims 22-24, 30, and 31.

Applicant's argument is not found persuasive. In view of the teachings of the newly cited reference of Badziong (*supra*) and for the reasons set forth above, claims 22-24, 30, and 31 of this application and the claims of the '059 patent are not patentably distinct from each other

Conclusion

[14] Status of the claims:

- Claims 22-24, 30-32, and 35-41 are pending.
- Claims 22-24, 30-32, and 35-41 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm. Application/Control Number: 10/076,632 Page 16

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David J. Steadman/ Primary Examiner, Art Unit 1656